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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,911	07/07/2003	Hiroshi Tone	239832US3CONT	4319

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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

ROANE, AARON F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,911

Applicant(s)

TONE ET AL.

Examiner

Aaron Roane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 8-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 8-21 and 23-25 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (USPN 5,879,378) in view of Miyashita (USPN 5,233,981) and in further view of Kuratomi et al. (USPN 4,747,841) and still in further view of Koiso et al. (USPN 5,425,975).

Regarding claim 6, Usui discloses a heat generator comprising: a heat generation portion comprising a heat generating composition (3) and a paper sheet (4), the heat generating composition including a metal powder, and a salt to be reacted with water and an adhesive layer (7) provided on a surface of the heat generator adapted to be applied to at least one of skin or mucosa of a user of the heat generator, see col. 1-24 and figures 1-4. Usui fails to explicitly recite that the heat generator, the heat generating composition and the metal powder and the salt to be reacted with water are adapted to discharge steam as the metal powder is oxidized. Additionally, Usui fails to recite the heat/steam generating

composition is disposed in pore-like structures of the paper sheet and the adhesive layer includes at least one opening through which the steam is discharged. Although Usui is silent regarding the heat generating composition adapted to generate steam, Usui implies that the exothermic heat generating composition generates steam (i.e., moisture) in col. 6, lines 17-21. Lacking an explicit recitation that the exothermic heat generating composition also generates steam, Applicant should note it is extremely well known in the art that many exothermic heat generating compositions also generate steam, moisture, water vapor. Miyashita illustrates this point very well. Miyashita discloses a hot compress device that uses many ingredients of the heat generating composition of Usui, see col. 3-10 and figures 1-9. Miyashita et al. teach providing an exothermic reaction that relies on the oxidation of a metal powder and the release of steam in order to provide heat that is prolonged and maintained via the release of steam, see col. 1-8, particularly col. 2-4. Kuratomi et al. disclose a heat/steam generating device and teach providing the device's adhesive layer (8) with holes (11) in order to provide ventilation of the steam/vapor through the adhesive layer and to the skin of the patient, see col. 1-4 and figures 1-8. Finally, Koiso et al. disclose an exothermic heating device for heating a body portion or food and teach providing the exothermic composition (comprising 4) in the pores/gaps (2) of a sheet-like structure (3) in order to assure "uniform distribution and firm support of the oxidizable metal powder or the heat-generating substance, the body is flexible, is free from one-sided distribution of the heat generating substance, and has excellent heat generating capability," see abstract and col. 1-7 and figures 1-7. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art

to modify the invention of Usui, as is well known in the art and taught by Miyashita, to provide an exothermic reaction that relies on the oxidation of a metal powder and the release of steam in order to provide heat that is prolonged and maintained via the release of steam, and also as taught by Kuratomi et al., to provide the device's adhesive layer with holes in order to provide ventilation of the steam/vapor through the adhesive layer and to the skin of the patient, and as further taught by Koiso et al., to provide the exothermic composition in the pores/gaps of a sheet-like structure in order to assure "uniform distribution and firm support of the oxidizable metal powder or the heat-generating substance, the body is flexible, is free from one-sided distribution of the heat-generating substance, and has excellent heat generating capability."

Regarding claim 8, Usui in view of Miyashita in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention.

Regarding claim 9, Usui discloses and teaches the use of an acrylic adhesive in order to provide the desired cohesion or tackiness, see col. 15-20. Since Applicant asserts on page 17, last paragraph, lines 4-9, that acrylic adhesives serve as a water-soluble adhesive, Usui in view of Miyashita in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention.

Regarding claims 10 and 12, Usui in view of Miyashita in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention.

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Regarding claims 11, 13 and 14, Usui in view of Miyashita in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention, see element (9) in Kuratomi et al. col. 3 and 4 and figure 1.

Regarding claims 15 and 16, Usui discloses an exothermic application pad and teaches including a cosmetic or pharmaceutical component in the adhesive layer in order to improve a local therapeutic effect, see claim 23 and col. 14, lines 26-60.

Regarding claim 25, Usui in view of Miyashita in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention. The embodiments disclosed by Kuratomi et al. certainly meet the recitation that the adhesive layer covers approximately 50% to approximately 99.9% of a surface to which the steam generator is applied.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (USPN 5,879,378) in view of Miyashita (USPN 5,233,981) and in further view of Kuratomi et al. (USPN 4,747,841) and still in further view of Koiso et al. (USPN 5,425,975) as applied to claim 16 above, and further in view of Kamiyama (USPN 6,669,953 B1).

Regarding claim 17, Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention except for reciting the use an adhesive layer that includes at least one of acidic mucopolysaccharides, chamomile, horse chestnut, ginkgo, hamamelis extract, vitamin E, nicotinic acid

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derivatives, and alkaloid compounds. Kamiyama discloses a drug delivery patch comprising an adhesive layer and teaches that the adhesive layer may contain vitamin E in order to increase its adhesive properties, see col. 4, line 60 through col. 5, line 2.

Therefore at the time of the invention it would have been obvious to one of ordinary skill to modify the invention of Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al., to use an adhesive layer contains vitamin E in order to increase its adhesive properties.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (USPN 5,879,378) in view of Miyashita (USPN 5,233,981) and in further view of Kuratomi et al. (USPN 4,747,841) and still in further view of Koiso et al. (USPN 5,425,975) as applied to claim 16 above, and further in view of Betrabet et al. (USPN 5,618,281).

Regarding claim 18, Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention except for reciting the use of an adhesive layer that includes at least one of horse chestnut, flavone derivatives, naphthalenesulfonic acid derivatives, anthocyanins, vitamin P, calendula officinalis, concholytic acid, silanol, Terminalia, Visnaga, and Majus. Betrabet et al. disclose a polysiloxane adhesive composition that is useful in attaching products to human skin and teach the use of silanol in the adhesive in order to induce crosslinking to prepare the desired polysiloxane adhesive composition and improve desired adhesive properties, see col. 2-3. Therefore at the time of the invention it would have been obvious to one of

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ordinary skill in the art to modify the invention of Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al., as taught by Betrabet et al., to use silanol in the adhesive in order to induce crosslinking to prepare the desired polysiloxane adhesive composition and improve desired adhesive properties.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (USPN 5,879,378) in view of Miyashita (USPN 5,233,981) and in further view of Kuratomi et al. (USPN 4,747,841) and still in further view of Koiso et al. (USPN 5,425,975) as applied to claim 16 above, and further in view of Hoffman et al. (USPN 6,190,689 B1).

Regarding claim 19, Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention except for reciting the use an adhesive layer that includes at least one of aminophylline, tea extract, caffeine, xanthine derivatives, inositol, dextranulfuric acid derivatives, horse chestnut, aescin, anthocyanadin, organiodine compounds, Hypericlm erectum, Spiraea japonica, Equisetum arvense, Rosmarinus officinalis, gingsen, Hedera rhombea, thomucase, and hyaluronidase. Hoffman et al. disclose a therapeutic device comprising hydrophilic pressure sensitive adhesive and teach the use of adhesives containing horse chestnut in order to treat contusions, distortions and/or haemorrhages or tea extracts in order to treat the circulatory system, see col. 4, line 57 through col. 5, line 16. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Usui in view of Miyashita and in further view of Kuratomi et al. and still in

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further view of Koiso et al., as taught by Hoffman et al., to use adhesives containing horse chestnut in order to treat contusions, distortions and/or haemorrhages or tea extracts in order to treat the circulatory system.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (USPN 5,879,378) in view of Miyashita (USPN 5,233,981) and in further view of Kuratomi et al. (USPN 4,747,841) and still in further view of Koiso et al. (USPN 5,425,975) as applied to claim 16 above, and further in view of Effing et al. (USPN 6,193,996 B1).

Regarding claim 20, Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention except for reciting the use an adhesive layer that includes at least one of indometacin, diclofenac, dl-camphor, flurbiprofen, ketoprofen, cayenne pepper extract, piroxicam, felbinac, methyl salicylate, and glycol salicylate. Effing et al. disclose a therapeutic device for the transdermal delivery of diclofenac and teach the use of adhesives containing diclofenac in order to improve the transdermal delivery of diclofenac for the treatment of inflammation of pain relief, see col. 2. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al., as taught by Effing et al., to use adhesives containing diclofenac in order to improve the transdermal delivery of diclofenac for the treatment of inflammation of pain relief.

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Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (USPN 5,879,378) in view of Miyashita (USPN 5,233,981) and in further view of Kuratomi et al. (USPN 4,747,841) and still in further view of Koiso et al. (USPN 5,425,975) as applied to claim 16 above, and further in view of Basedow et al. (USPN 6,198,017 B1).

Regarding claim 21, Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention except for reciting the use an adhesive layer that includes polyol. Basedow et al. disclose medical pressure-sensitive adhesives and teach the use of adhesives containing polyol in order to provide improved adhesion to dry, moist and wet skin, see col. 1, line 43 through col. 2, line 65. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al., as taught by Basedow et al., to use adhesives containing polyol in order to provide improved adhesion to dry, moist and wet skin.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usui (USPN 5,879,378) in view of Miyashita (USPN 5,233,981) and in further view of Kuratomi et al. (USPN 4,747,841) and still in further view of Koiso et al. (USPN 5,425,975) as applied to claim 16 above, and further in view of Tsutsumi (USPN 6,841,716 B1).

Regarding claim 23, Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al. disclose the claimed invention except for reciting the use an adhesive layer that includes polyol. Tsutsumi discloses a device having an adhesive layer and teach the use of adding calcium thioglycolate to serve as an absorption accelerator of the pressure sensitive adhesive in order to improve the penetration of a drug through the skin, see col. 4, lines 10-52. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al., as taught by Tsutsumi, to use calcium thioglycolate to serve as an absorption accelerator of the pressure sensitive adhesive in order to improve the penetration of a drug through the skin.

Regarding claim 24, Usui in view of Miyashita and in further view of Kuratomi et al. and still in further view of Koiso et al. in further view of Tsutsumi disclose the claimed invention except for explicitly reciting that adhesive layer contains an autonomic regulating agent that includes γ -oryzanol. Tsutsumi does however disclose that autonomic agents are combined with the pressure sensitive adhesive whenever a pressure sensitive adhesive is combined with a drug to achieve a desired effect, see col. 4, lines 38-53. At the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to specifically use γ -oryzanol as an autonomic regulating agent because Applicant has not disclosed γ -oryzanol provides an advantage, is used for a particular purpose, or solves a stated problem over other autonomic

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regulating agents. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any of a wide variety of autonomic regulating agents as opposed to the specific use of γ -oryzanol, because they both produce the same desired effect.

Allowable Subject Matter

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Regarding Applicants amendments to claims 17-24, the rejections under 35 U.S.C. 112 have been overcome.

Applicant's arguments with respect to claim 6 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
August 30, 2005

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER